



INTERPRETATION OF BARDA'S PRIORITIES FOR 2023: PREPAREDNESS FOR THE NEXT PANDEMIC THREAT

February 14, 2023

BDO USA, LLP, a Delaware limited liability partnership, is the U.S. member of BDO International Limited, a UK company limited by guarantee, and forms part of the international BDO network of independent member firms.



Agenda for Today



Introductions



Overview



BARDA Industry Day Takeaways and Priorities

- ▶ BARDA Strategic Plan



BARDA's New Initiatives

- ▶ Domestic Manufacturing
- ▶ Supply Chain Security
- ▶ Antimicrobial Resistance



Positioning to Support BARDA Initiatives

- ▶ Key Considerations

With You Today



CHRISTOPHER HOUCHENS

Director
HHS/OS/ASPR/BARDA
Division of CBRN
Countermeasures

christopher.houchens@hhs.gov



ADEY PIERCE-WATKINS

Director
BDO Biodefense &
Government Contracts

apierce@bdo.com



MATT SIGMUND

Director
BDO Biodefense &
Government Contracts

msigmund@bdo.com



TRAVIS TAYLOR

Vice President
SMI
Life Science Practice

travis@strategicmi.com

OVERVIEW

Learning Objectives

PARTICIPANTS WILL

- ▶ Review of BARDA Industry Day Takeaways and Priorities based on the BARDA Strategic Plan
- ▶ Understand new initiatives related to domestic manufacturing, supply chain security and antimicrobial resistance
- ▶ Understand how potential industry partners can best positioned to support new BARDA initiatives



HHS/OS/ASPR/BARDA

Christopher Houchens
BARDA CBRN Director



BARDA's FY23 Initiatives

Christopher Houchens, Ph.D.

Director, Division of Chemical, Biological, Radiological, and Nuclear (CBRN)
Medical Countermeasures

Biomedical Advanced Research and Development Authority (BARDA), Administration for
Strategic Preparedness and Response (ASPR), Department of Health and Human Services
(DHHS)

BDO Life Science Biodefense Webinar, 14 February 2023

Unclassified

The BARDA Model

BARDA develops and makes available medical countermeasures (MCMs) by forming unique public-private partnerships to drive innovation off the bench to the patient to save lives.



Flexible, nimble authorities

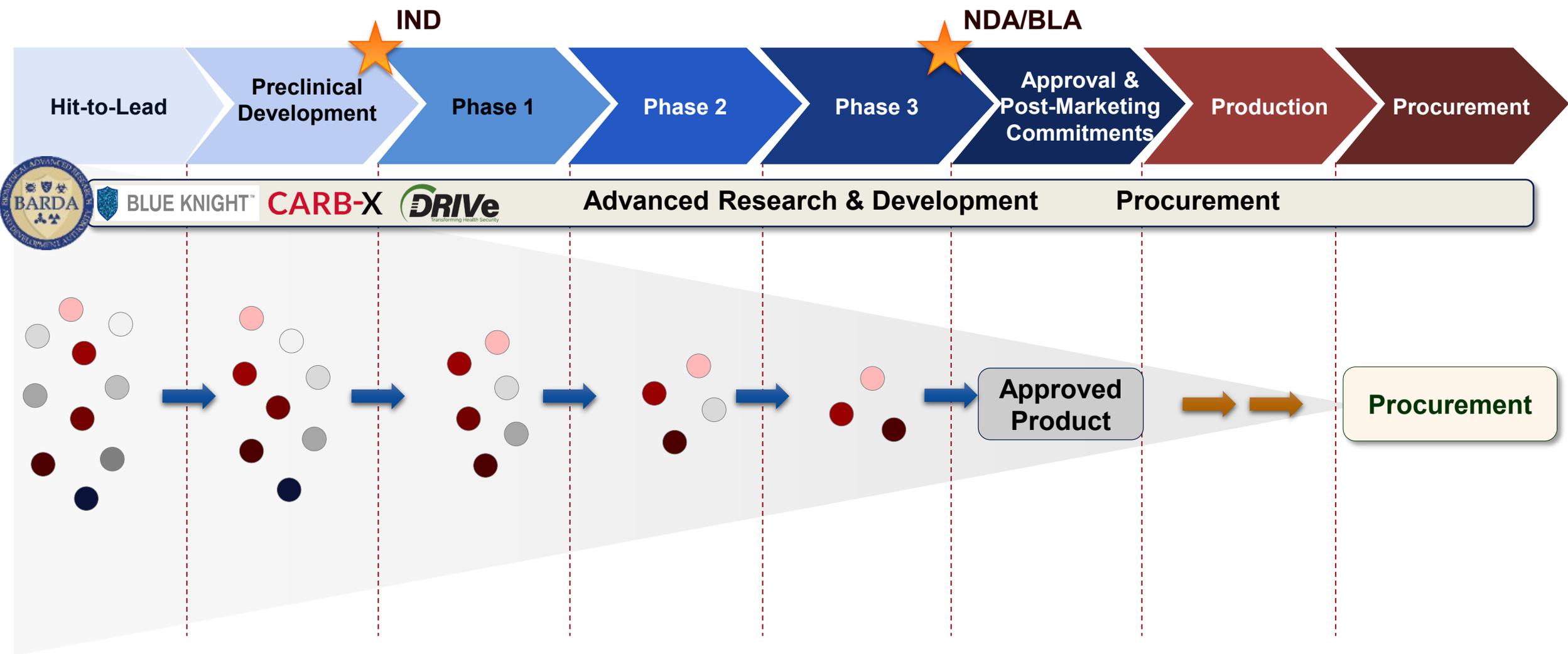
Multi-year funding

Cutting edge expertise

Facilitate partnerships

Promote innovation

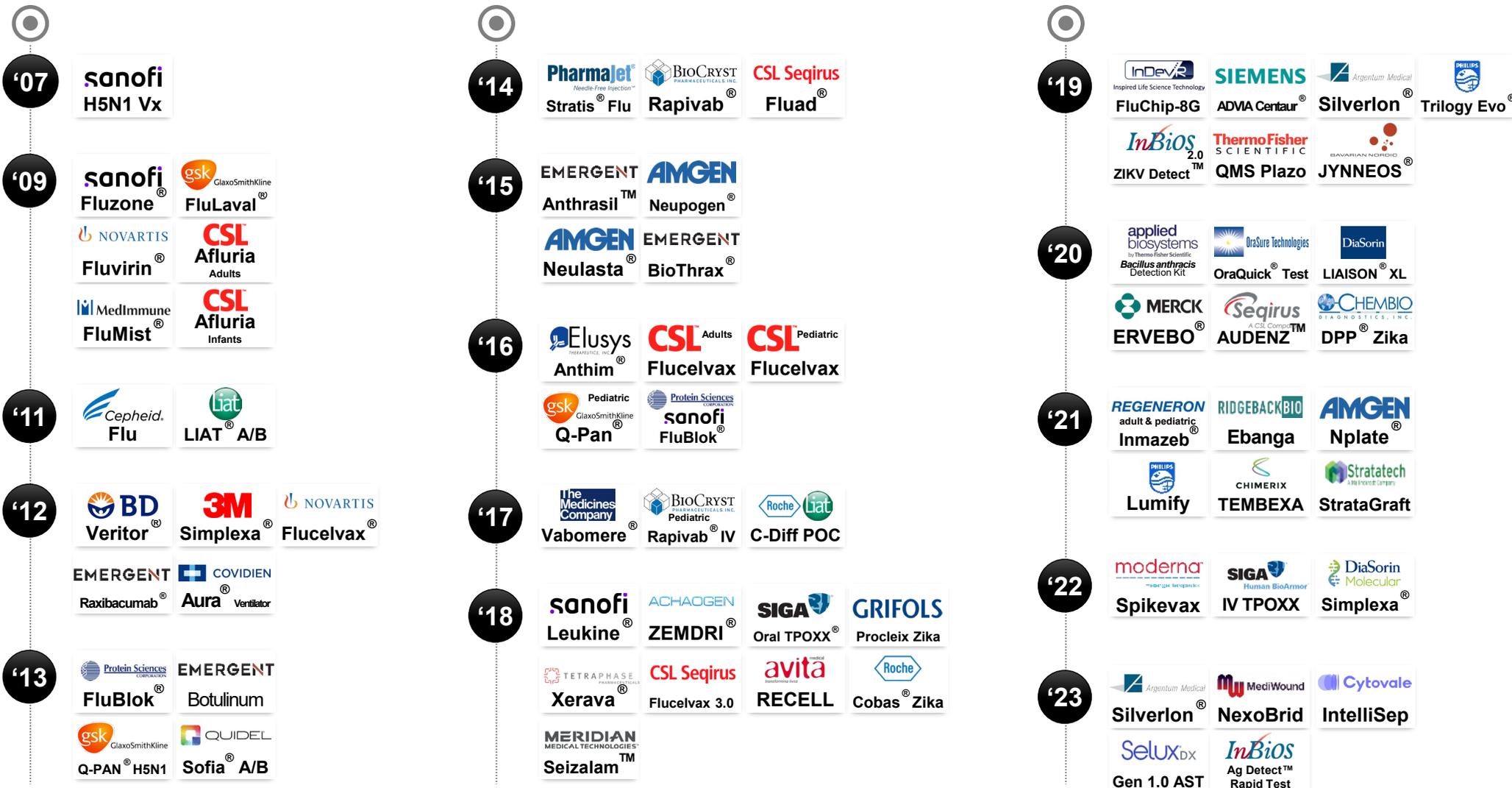
BARDA's Medical Countermeasure Development Pipeline



Our Government Partners



69 FDA Approvals, Licensures, and Clearances

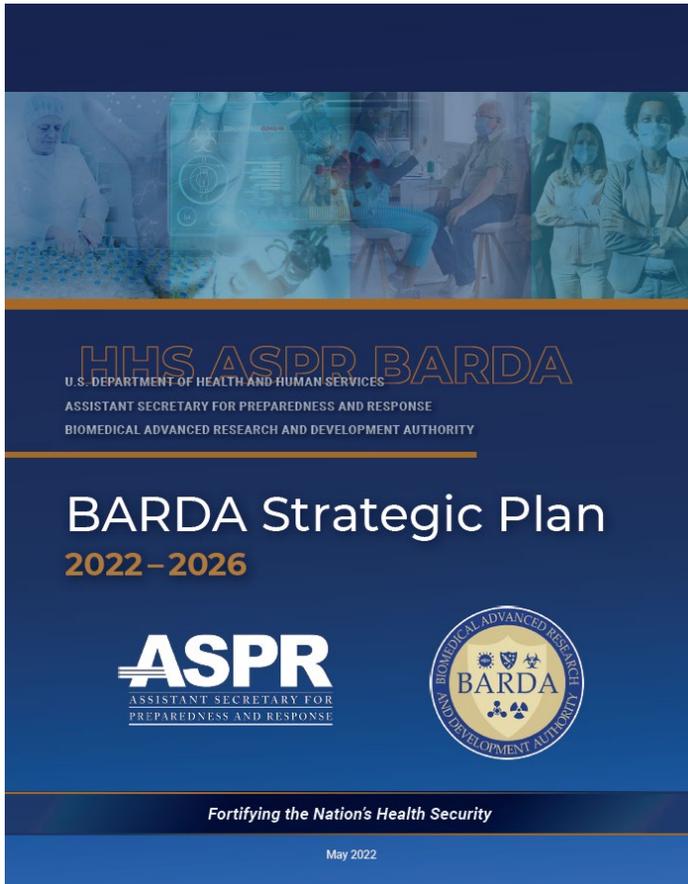


Device (7)
Therapeutic (22)
Diagnostic (19)
Vaccine (21)

BARDA Strategic Plan 2022-2026

The 2022-2026 document serves to effectively communicate our mission and vision to BARDA stakeholders

Learn more: www.medicalcountermeasures.gov/barda/strategic-plan/



Goal 1 – Preparedness: Rapidly develop safe, effective medical countermeasures accessible to all Americans



Goal 2 – Response: Enhance and maintain a sustainable, mission-ready response posture



Goal 3 – Partnerships: Leverage mechanisms to foster flexible partnerships



Goal 4 – Workforce: Build and support a world class workforce



BARDA's Role in Future Pandemic Preparedness



American Pandemic Preparedness: Transforming Our Capabilities

September 2021

I. Transforming our Medical Defenses

Goal: Have the ability to rapidly make effective vaccines against any virus family.

Goal: Have a range of therapeutics suitable for any virus family, available before a pandemic or readily created during a pandemic.

Goal: Have simple, inexpensive, high-performance diagnostic tests available at large scale within weeks after the recognition of an emerging pandemic threat.

<https://www.whitehouse.gov/briefing-room/statements-releases/2021/09/03/fact-sheet-biden-administration-to-transform-capabilities-for-pandemic-preparedness/>

Biomedical Advanced Research and Development Authority (BARDA) Office of the Director

MEDICAL COUNTERMEASURES (MCM) PROGRAM

Chemical, Biological, Radiological and Nuclear (CBRN) MCMs



Influenza & Emerging Infectious Diseases (IEID)



Detection, Diagnostics, & Devices Infrastructure (DDDI)



Division of Research, Innovation, and Ventures (DRIVE)



Pharmaceutical Countermeasures Infrastructure (PCI)



MEDICAL COUNTERMEASURES SUPPORT SERVICES PROGRAM

Regulatory and Quality Affairs (RQA)



Clinical Development (DCD)



Nonclinical Development (DNCD)



CONTRACT MANAGEMENT & ACQUISITIONS AND BUSINESS PLANNING AND STRATEGY

Medical Countermeasures Development Services



Medical Countermeasures Support Services



Business Operations and Compliance



DRIVE Acquisitions and Partnerships



Influenza & Emerging Infectious Disease Division (IEIDD)



VISION

Robust portfolio of MCMs for the prevention, detection, and treatment of influenza and emerging infectious diseases



STRATEGY



New, faster, and better therapeutics, vaccines, and diagnostics for influenza



Increase and sustain domestic production capacity



Pandemic Readiness through timely and accessible vaccination strategies



FUTURE DIRECTIONS

Increase health impact of influenza therapeutics by developing host-targeted therapeutics

Invest in sustainable technologies for more effective vaccines, faster manufacturing, distribution, and administration

Smart implementation strategies, including expanded licensure of pre-pandemic vaccines to include additional strains, subtypes, and special population indications

Increase pandemic readiness by bringing pre-exposure prophylaxis drugs to licensure

Detection, Diagnostics, & Devices Infrastructure (DDDI)



VISION

Develop diagnostics and devices across BARDA's threat portfolio and add new diagnostic capabilities for a faster pandemic response.



STRATEGY



Leverage routine health care capabilities and manufacturing capacity



Build essential relationships, both programmatic & financial



Support surge testing with multi-use domestically produced platforms



FUTURE DIRECTIONS

Move testing closer to the patient while preserving lab testing capability

Stimulate emergence of new technologies with big health security impact

Rapid domestic test manufacturing capability with partners, in lieu of stockpiling

Make threat agnostic diagnostics a reality

Division of Research, Innovation, and Ventures (DRIVE)



VISION

Create novel, effective life-saving MCMs that are available to everyone who needs them when they need them.



STRATEGY

Identifying and de-risking the world's most promising technologies and capabilities to develop tomorrow's MCMs.



FUTURE DIRECTIONS

Continue to expand the Global Health Security investment portfolio of the BARDA Ventures partnership with GHIC

Launch a decentralized clinical and healthcare network to enhance rapid response capabilities

Continue to grow DRIVE's EZ-BAA portfolio of partners across our 13 R&D programs

Launch Accelerator Network 2.0 with an increased focus on rapidly developing emerging MCMs during emergency response

Public-Private Partnership between BARDA and Global Health Investment Corporation



OVERVIEW

- Using venture capital practices to invest in technologies to bolster global health security, pandemic response, and health emergency preparedness



GOALS OF PARTNERSHIP

- Increase speed and flexibility of funding
- Identify and invest in technologies to strengthen health security
- Co-invest with private sector



HEALTH SECURITY IMPACT

- Mission aligned with BARDA's strategic priorities
- GHIC mobilizes additional capital, structures terms of investments
- Double bottom line – seeking impact and financial return



MAJOR ACCOMPLISHMENTS

- Completed 9 investments across BARDA mission framework
- \$85M BARDA funds committed for investment
- 8:1 dollars of additional investment at the time of GHIC investment



FUTURE DIRECTION

- Continue to expand investment portfolio
- Guide portfolio companies towards BARDA mission
- Re-invest financial proceeds to advance health security

Pharmaceutical Countermeasures Infrastructure (PCI)



VISION

Strengthened and enhanced biopharmaceutical manufacturing capabilities that enable fast and effective responses to public health emergencies



STRATEGY



Product Development Process Expertise



Capacity Infrastructure Contracts

BIOPHARMACEUTICAL MANUFACTURING PARTNERSHIP



- » Pandemic-scale drug substance manufacturing (mfg)
- » Supporting targeted innovations in advanced mfg
- » Enhancing biopharmaceutical workforce development
- » Strengthening raw materials supply chain

CONTRACT DEVELOPMENT AND MFG ORGANIZATION (CDMO) NETWORK



- » Ready and vetted network of CDMOs to strengthen drug product & fill/finish response capabilities
- » Securing national supply of essential medicines through small molecule and API mfg

PANDEMIC VACCINE PREPAREDNESS CAPABILITY & RESPONSE



- » Domestic capacity expansion targeting key inputs in biomanufacturing
- » Monitoring/tracking supply chain for pandemic response scenarios



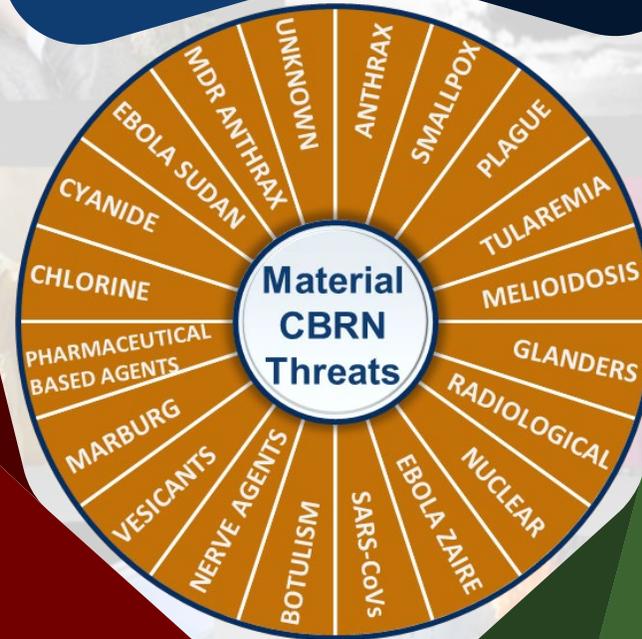
Division of CBRN Medical Countermeasures

CBRN MISSION

Make Available **at Least One** Countermeasure for **ALL CBRN Material Threats**

Develop innovative MCMs for unknown threats

All CBRN Branches



Radiological & Nuclear MCMs

Burn & Blast MCMs

Chemical MCMs

Invest in MCMs to *treat the injury, not the threat*

Antivirals & Antitoxins

Antibacterials

Vaccines

Deliver novel MCMs against bacterial & viral threats

Chemical MCMs Program



END GOAL

Ensure that MCMs for chemical injury are readily available for the end user

STRATEGIC OBJECTIVES

Develop a threat-agnostic pipeline of MCMs

- Broad spectrum use for chemical and conventional indications
- Ease of availability during chemical emergency

Repurpose common drugs for chemical indications

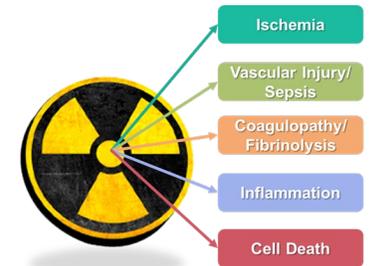
- Allows for use of readily available drugs for chemical injury
- Far forward positioned drugs: already with the end-user

Provide user-focused solutions

- Ensure that first responders have the products they need
- Create a communication channel directly with the end user

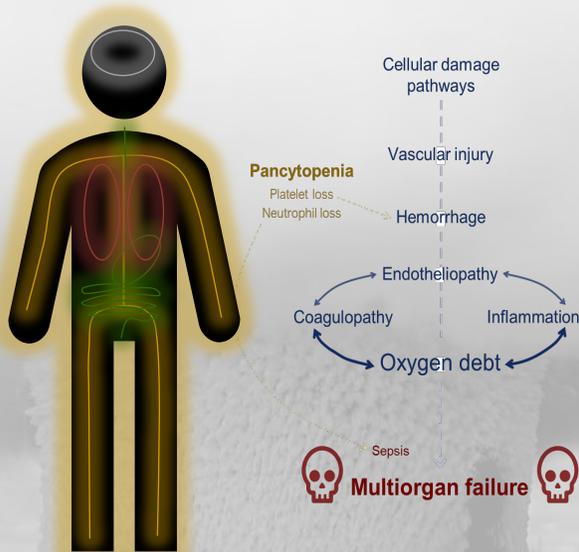
Radiological & Nuclear MCMs Program

FOCUS AREAS & STRATEGIC ACTIONS



GOAL

Improve **radiation injury and trauma** health outcomes for all victims of nuclear detonations and radiation exposure



- **Hematopoietic:**

- Improve all aspects of hematopoietic injury (radiation and trauma induced) through targeted natural history

- **Innovation:**

- Blood products – sustainable, robust traditional and next generation blood products
- Enabling technology development (e.g., tissue chips)
- Develop targeted natural histories for unmet areas of pathophysiology (e.g., ischemia, GI, lung)
- Employ new technologies and treatment for robust systemic care

- **Repurposing:**

- Leverage commercially available products
- Leverage across threat spaces
- Target underserved and special populations (e.g., pediatrics)

- **Preparedness and Sustainability:**

- Repurpose existing commercial products and enable vendor managed inventories with stock rotation
- Develop new products with relevant commercial capacity in regular health care settings
- Drive creation of new essential market space (e.g., pre-hospital)
- Provide interagency support for disaster response



Burn and Blast MCMs Program

Goal: Build national preparedness for range of threats with burn & blast consequences

➤ MCM development focus

- Comprehensive real-world solutions
- Adoption in routine care
- Sustainable strategy for the long term
- Demonstrable value proposition
- Adaptable to inherent challenges in health care

Intended Impact



Traumatic Brain Injury (TBI)

Diagnosis; Degree of Severity; Detect ICP

Cervical & Spinal Cord Injury (SCI)

Diagnosis & Severity

Lung Injury: multiple etiologies

Prognosis of disease and injury

Internal / Non-Compressible Hemorrhage and Penetrating Injuries

Primary interventions; Severity assessment

Fracture Detection *without X-rays*

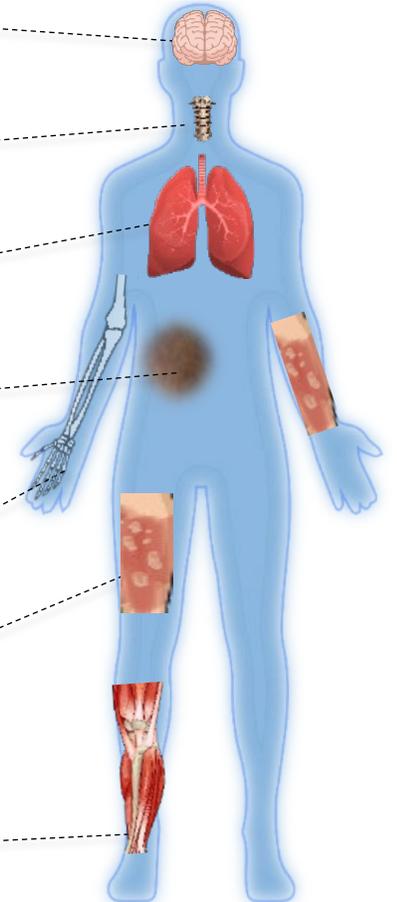
Soft Tissue Injuries *missed in X-rays*

Deep Dermal Burns

Detect Severity; Definitive care across the burn care continuum

Compartment Syndrome

Non-invasive Detection

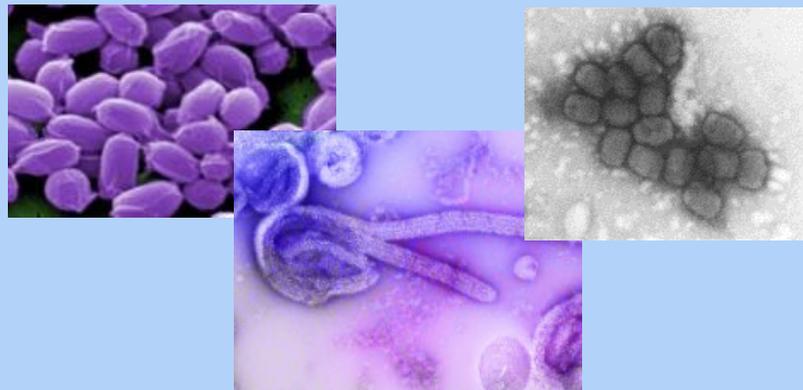


Vaccines Program

PAST

ADDRESSING THE URGENT DHS CLASS A THREAT AGENTS

- Early stage MCMs: Anthrax, Marburg Virus, Sudan Ebola Virus
- Late stage MCMs: Anthrax, Zaire Ebola Virus
- Licensed MCMs: Smallpox, Monkeypox, Anthrax, Zaire Ebola Virus
- Established baseline of preparedness



PRESENT

BUILDING ON PREPAREDNESS BASELINE

- Addressing VHF
- Improved sustainability: lyophilized formulations, flexible procurement strategies
- Enhanced operational performance - special populations, boosting strategies, dose-sparing, stability



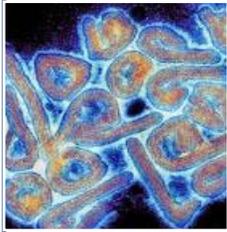
FUTURE

NEXT PRIORITY THREATS + INNOVATING THE PIPELINES

- Maintain flexibility to target new threats when needed
- Emphasize technologies that are amenable to rapid progress from target ID to clinical studies
- Invest in technologies that will enable distributed manufacturing



Antivirals and Antitoxins Program



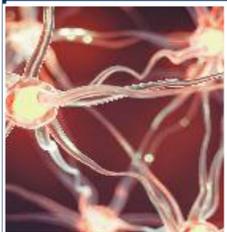
Filovirus: 2 licensed therapeutic mAbs

- Advance **MARV** and **SUDV** mAbs to licensure
- Identify and develop two broad acting antivirals to reduce case fatality in severe infection and reduce persistent infection
- Support procurement of approved MCMs



Smallpox: 2 licensed therapeutics

- Advance mAb smallpox antibody cocktail to serve as risk mitigation for resistance and for treatment of special populations
- Procure multiple formulations of two smallpox antivirals



Botulinum Neurotoxins: 1 licensed antitoxin

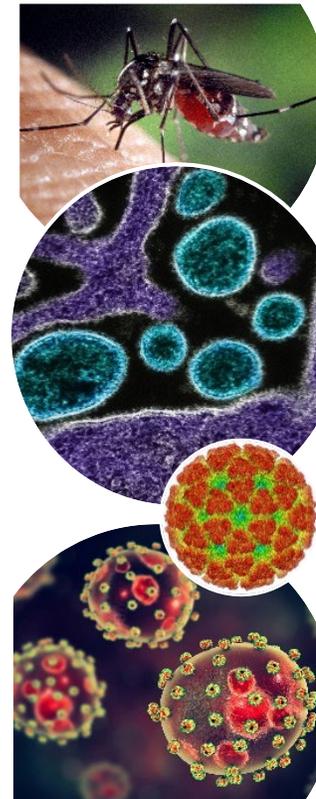
- Develop next-gen mAb cocktail against multiple serotypes of BoNT
- Explore feasibility of host-directed MCM to reduce dependency on mAb cocktails



Anthrax: 3 licensed antitoxin antibody products

- Support testing of mAb products to inform operational utility post-expiry
- Support maintenance of product licensure through support for PMR/PMCs

Planning for the Future:



Develop MCMs to prepare for **future threats**

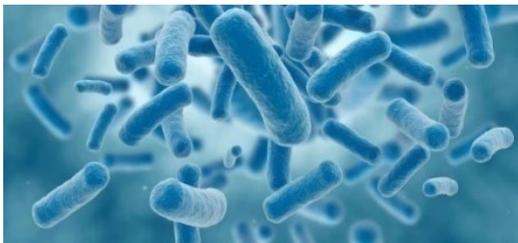
- Characterize and develop threat-agnostic MCMs to treat **symptoms and syndromes** associated with infection
- **Develop broad spectrum antivirals** that have efficacy against multiple species within a family or multiple viral families

Antimicrobials Program



MISSION

- » Reduce the morbidity and mortality caused by a biothreat or antimicrobial resistant (AMR) bacterial infection following a mass casualty event or a disease outbreak



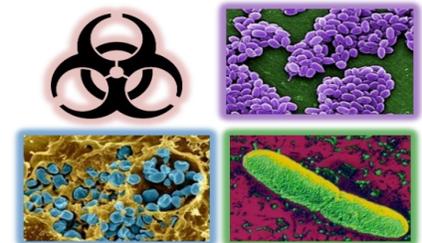
AMR PRIORITIES

- » CDC urgent and serious threats
- » Hospital-associated and community-acquired drug-resistant infections (pneumonia, bloodstream infections)
- » **Fungal infections**
- » Biothreat pathogens
 - » (MDR) *Bacillus anthracis*
 - » *Burkholderia pseudomallei*
 - » *Burkholderia mallei*
 - » *Francisella tularensis*
 - » *Yersinia pestis*
- » Oral formulations
- » Underserved/special populations

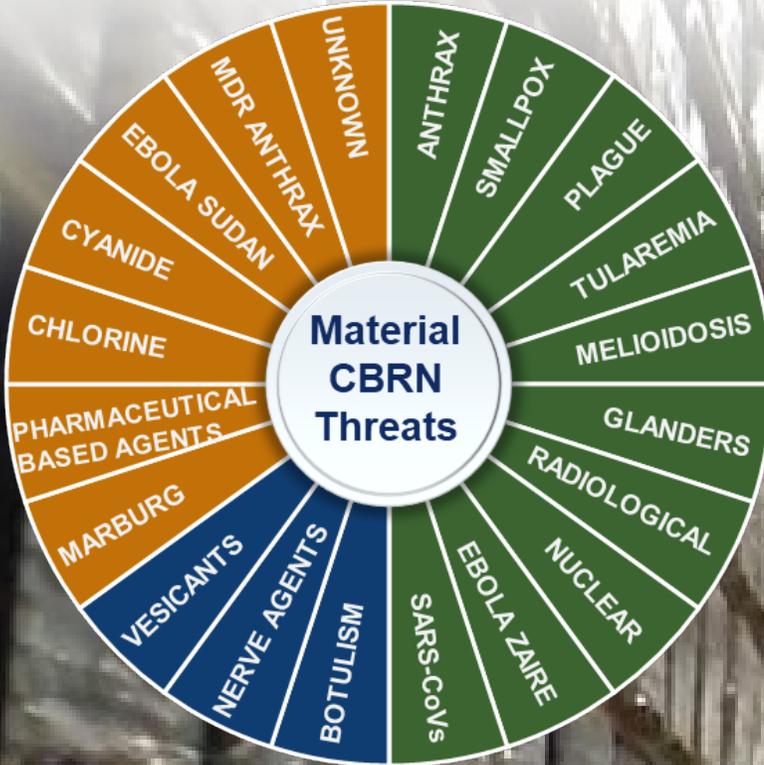


APPROACH

- » Circumvent existing mechanisms of resistance
- » Extend the useful lifespan of existing drugs
- » Reduce side effects by minimizing collateral damage
- » Enable more sustainable treatment approaches



Project BioShield: A Commitment



■ ≥1 product procured
■ 1 product procured
■ BARDA is developing MCM(s)

36

Products Supported

26

New Products Procured

CBRN's 27 FDA Approvals, Licensures, and Clearances



<p>EMERGENT NDC 71655-103-01 Raxibacumab injection</p>	<p>EMERGENT BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G)-(EQUINE)]</p>	<p>EMERGENT Anthrax Immune Globulin Intravenous (human) Anthrasil </p>	<p>Elusys therapeutics, inc. ANTHIM oblitoxikimab </p>	<p>Melinta VABOMERE™ meropenem and vaborbactam</p>	<p>SANOFI Leukine® sargramostim</p>	<p>Argentum Medical SILVERLON Sulfur mustard</p>	<p>MERCK ERVEBO</p>	<p>AMGEN Nplate® romiplostim </p>	<p>SIGA TPOXX® IV (tecovirimat)</p>
		<p>AMGEN NEUPOGEN® FILGRASTIM</p>			<p>ACHAAGEN ZEMDRI™ (plazomicin) Injection</p>	<p>ThermoFisher SCIENTIFIC QMS Plazomicin Immunoassay</p>	<p>REGENERON Inmazeb® colistib, meropenem, and plazomicin - high potency</p>	<p>PHILIPS Lumify</p>	<p>Argentum Medical SILVERLON Cutaneous Radiation Injury</p>
		<p>AMGEN Neulasta® (pegfilgrastim) injection</p>			<p>SIGA TPOXX® Oral (tecovirimat)</p>	<p>BAVARIAN NORDIG JYNNEOS</p>	<p>RIDGEBACKBIO ebanga</p>	<p>EMERGENT TEMBEXA™ brincidofovir</p>	<p>MediWound NexoBrid® (anacoulase-bcbb)</p>
		<p>EMERGENT ANTHRAX VACCINE ADSORBED BioThrax®</p>			<p>TETRAPHASE PHARMACEUTICALS XERAVA™</p>			<p>Stratatech A Mallinckrodt Company StrataGraft® alginate chitosan hydrogel for skin and bone</p>	
					<p>avita transforming area RECELL®</p>				
					<p>MERIDIAN Seizalam™</p>				

CBRN Priorities



Develop host-based threat-agnostic MCMs

Develop broad-spectrum antivirals with efficacy against multiple viruses



Develop MCMs to detect and treat blast injuries

Invest in development of innovative antifungals



Invest in flexible technologies for vaccine manufacturing

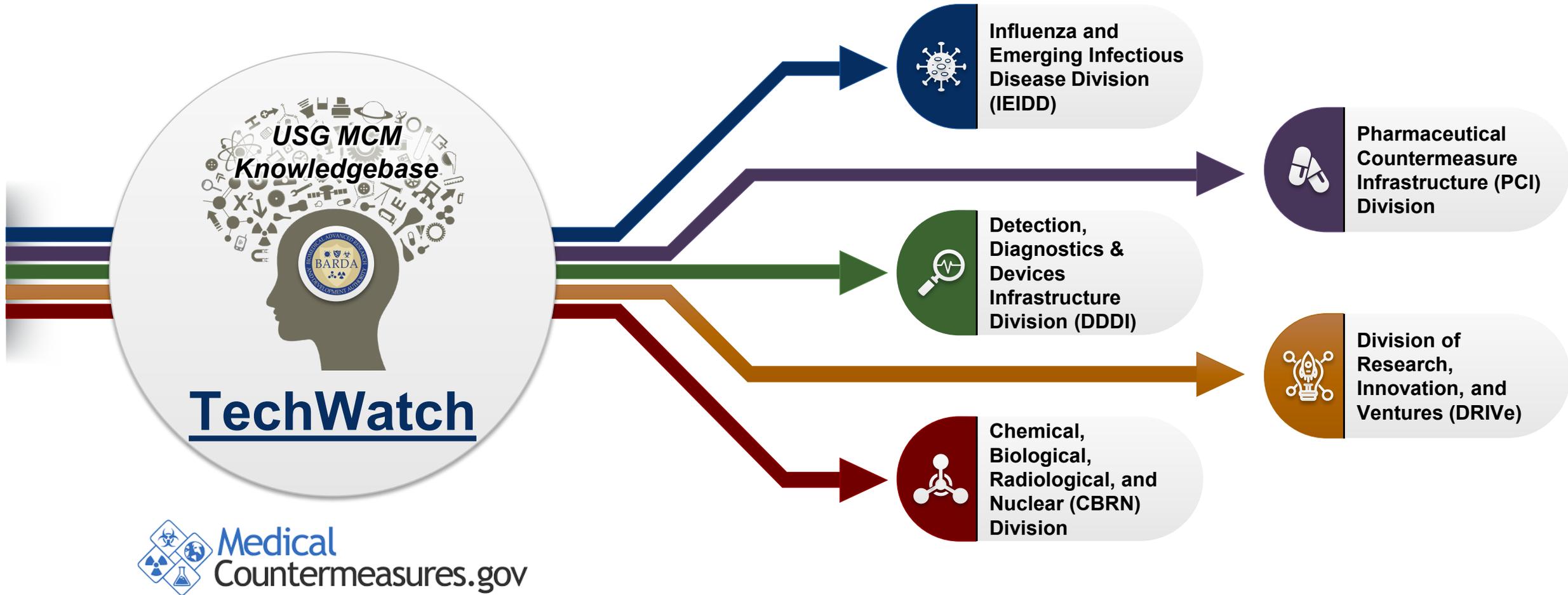


Improve MCM CONOPs and sustainability



Ultimate Goal:
Ensure the nation is prepared to rapidly respond to any CBRN threat

TechWatch





[medicalcountermeasures.gov](https://www.medicalcountermeasures.gov)
Portal to BARDA: Register to request a TechWatch meeting!



[sam.gov/](https://www.sam.gov)
Official announcements and info for all government contract solicitations



[phe.gov/BARDA](https://www.phe.gov/BARDA)
Program description, information, news, announcements



drive.hhs.gov
Learn about DRIVE, including our Accelerator Network and EZ BAA



www.usajobs.gov
Join the team!



@BARDA



Biomedical Advanced Research and Development Authority



@BARDAGOV

PROGRAM MANAGEMENT PERSPECTIVE

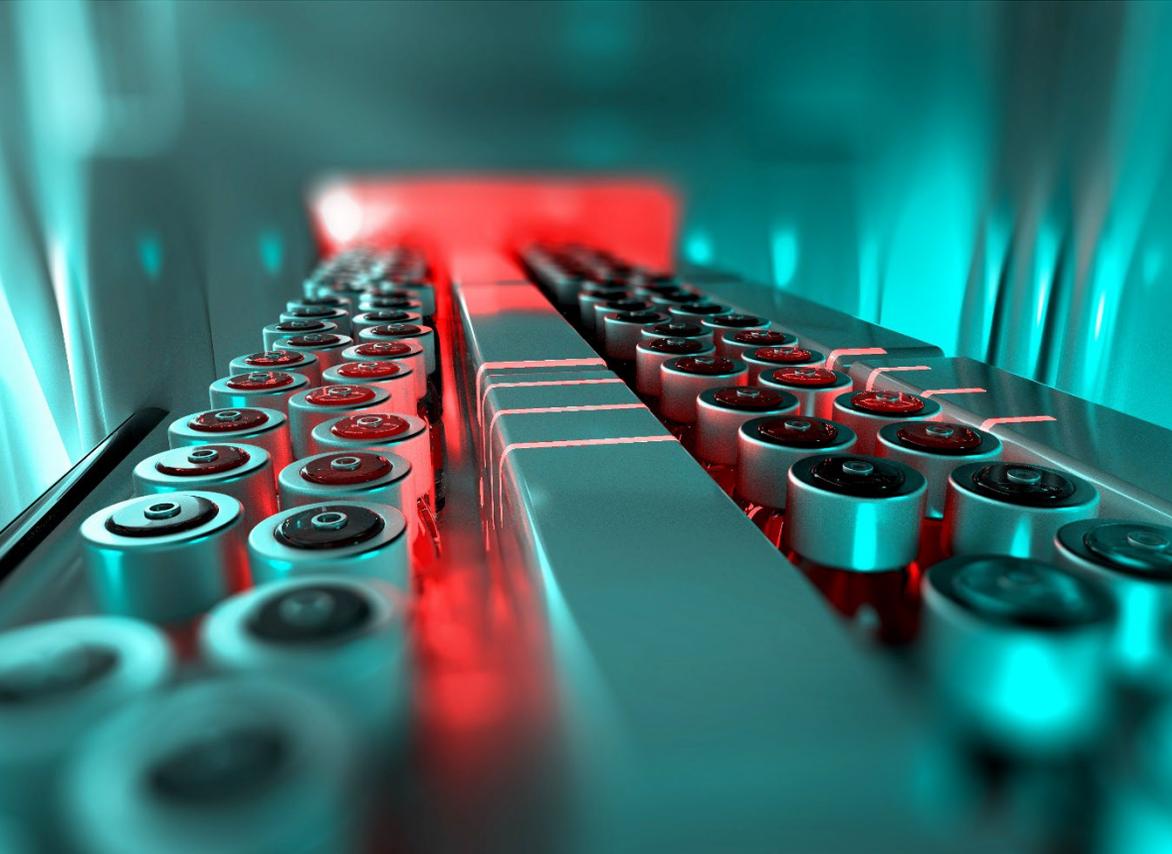
Life Sciences Positioning to Support BARDA Initiatives

PHEMCE organizations and agencies work to optimize the Nation's preparedness for public health emergencies regarding the development, manufacturing, stockpiling, and administration of medical countermeasures.

Federal Agencies Coordination Supporting MCM Development



Administration Actions Informing BARDA Priorities



- ▶ Executive Order Advancing Biotechnology and Biomanufacturing Innovation
 - Bolster federal investment in key research and development areas of biotechnology and biomanufacturing
 - Improve and expand domestic biomanufacturing production capacity and processes
 - Biotechnology and biomanufacturing workforce training
 - Regulatory streamlining and clarification
- ▶ Public Health and National Emergency Declarations ending May 11

FUNDING

FY2023 Omnibus

HHS PREPAREDNESS

\$950M

Advanced Research and
Development of
Medical Countermeasures
(BARDA)

\$965M

Strategic National
Stockpile

\$335M

Pandemic Influenza
Preparedness

BEST POSITIONING

Alignment with Federal Priorities

- ▶ Assess relevant Broad Agency Announcement (BAA) Topic Area(s) of Interest
 - Eligibility
 - Area of Interest priorities/requirements
 - Technological Maturity
- ▶ Actively monitor updates/amendments, new initiatives, new partnerships
- ▶ Communicate your solution to the relevant Technical Point of Contact listed in BAA Area of Interest
 - Be clear about Technology Readiness Levels and where your technology is (is your technology too early?)
- ▶ Become familiar with the Acquisition Process
- ▶ Request a TechWatch meeting prior to any White Paper submission
- ▶ Submit solicited proposals

Office of Biomedical Advanced Research and Development
Authority (BARDA) Broad Agency Announcement (BAA)



BAA-18-100-SOL-00003

Amendment 37
January 13, 2023

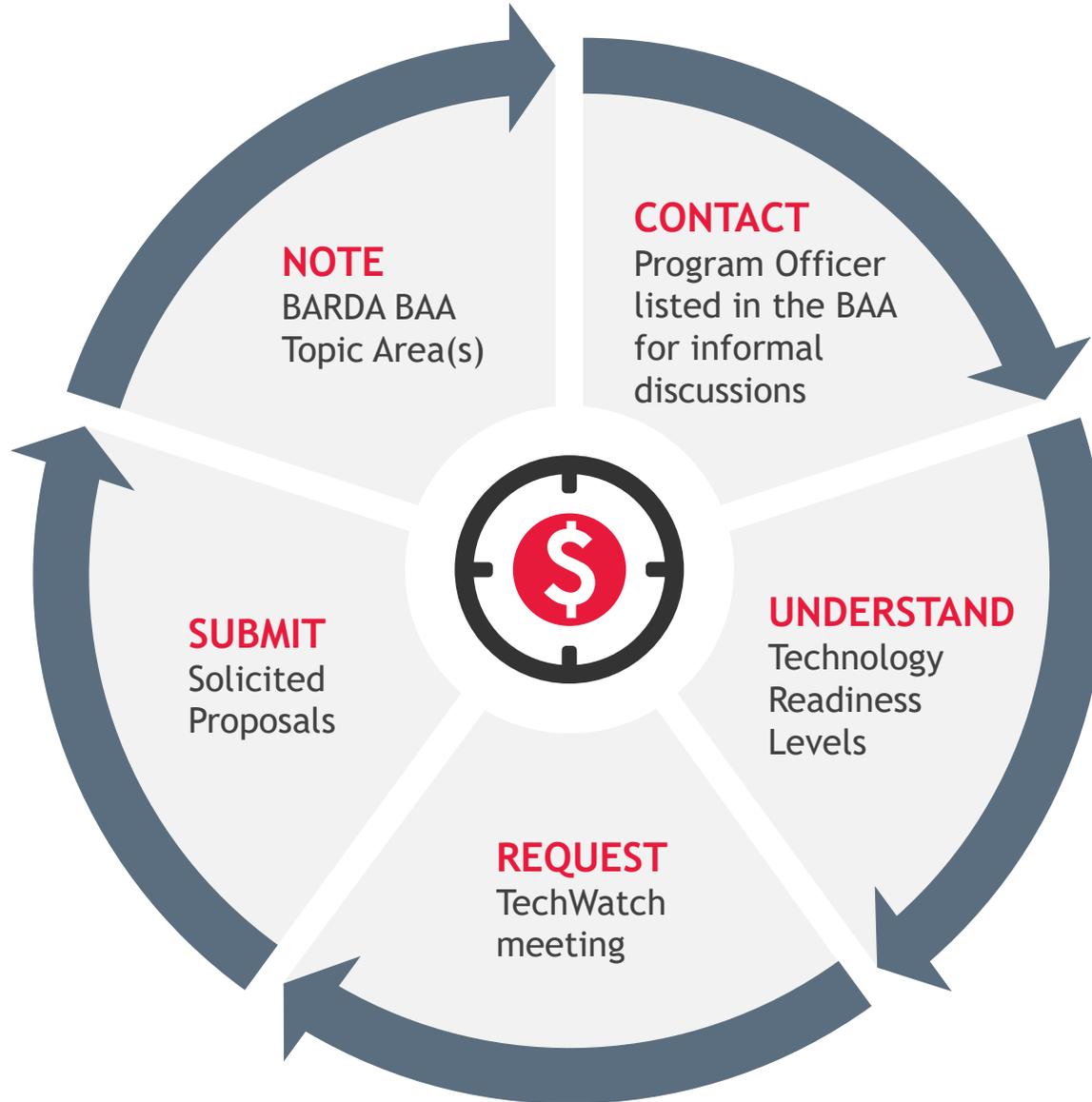
Biomedical Advanced Research Development Authority (BARDA)

Contracts Management & Acquisition (CMA)

200 C Street SW

Washington, DC 20201

Best Practices for Engaging with BARDA



Too Early for BARDA Funding?

FEDERAL PROGRAMS

- ▶ Congressionally Directed Medical Research Program (CDMRP) [LINK ▶](#)
- ▶ NIH SBIR Program [LINK ▶](#)
- ▶ 2023 NIAID Omnibus BAA: Biodefense & Emerging Pathogens [LINK ▶](#)
- ▶ Preclinical Services at National Institute for Allergy and Infectious Diseases [LINK ▶](#)
- ▶ DOD Medical Technology Enterprise Consortium [LINK ▶](#)

Congressional Appropriations strategy to create a \$5-10 million pot of money to support R&D programs





Preparing Your Organization to Partner with the USG

PARTNERING WITH THE USG

Risks and Rewards



RISKS

Programmatic & Budgetary

Contractual

Legal/Regulatory



REWARDS

Non-Dilutive Funding

USG as a Customer

Non-Commercial
Product Development

Partnering with the USG Programmatic and Budgetary Considerations

PROPOSAL → EXECUTION

- ▶ Scope alignment w/ USG need
- ▶ Timelines
- ▶ Cost/price

PROJECT → PROGRAM MANAGEMENT

- ▶ Unique U.S. Government requirements
- ▶ Translation of internal program management methodologies to USG requirements



PARTNERING WITH
THE USG
**Accounting &
Finance**



PROJECT ACCOUNTING

- ▶ Direct Costs
- ▶ Indirect Costs



TIMEKEEPING



PROCUREMENT

- ▶ Price reasonableness
- ▶ Vendor flowdown requirements

COMPLIANCE WITH T&C'S REQUIRES INVESTMENT



HR

- ▶ Employment reporting requirements
- ▶ Service Contract Act
- ▶ Davis Bacon Act



IT

- ▶ Cybersecurity Maturity Model Certification (CMMC)
- ▶ NIST SP 800-171

COMPLIANCE WITH T&C'S REQUIRES INVESTMENT



Property Ownership Considerations

- ▶ Title vesting
- ▶ Disposition of equipment upon award completion
- ▶ Opportunities for alternative approaches



Representations & Certifications

- ▶ SAM.gov registration



Government As a Long-term Customer

- ▶ Most Favored Customer Status
- ▶ DPA Rated Orders

Wrap Up

LEARNING OBJECTIVES

Wrap-Up

PARTICIPANTS WILL

- ▶ Review of BARDA Industry Day Takeaways and Priorities based on the BARDA Strategic Plan
- ▶ Understand new initiatives related to domestic manufacturing, supply chain security and antimicrobial resistance
- ▶ Understand how potential industry partners can best positioned to support new BARDA initiatives



Questions?

